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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,037	12/31/2001	Avigdor Levanon	10793/44	8494

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,037	LEVANON ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-13,153,154,156,157 and 164 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-13,153,154,156,157 and 164 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/6/02 1/27/03.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: IDS 6/7/04; 7/14/05 & 8/28/05.

DETAILED ACTION

Claims 1, 5, 14-152 and 157 have been canceled. Claims 2, 3, 6, 7 and 11-13 have been amended. Claims 2-4, 6-13, 153, 154, 156, 157 and 164 are pending and under consideration.

Sections of Title 35, U.S. Code not found in this action can be found in a previous action.

It is noted that the previous Office action was made final, but that the Office Action Summary indicated a non-final rejection. Although the Office action governs when there are inconsistencies between an Office action and the Office action summary sheet, the intended finality of the prior office action will be withdrawn in order to provide customer service and advance prosecution.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "synthetic isolated epitope" in claim 12 lacks antecedent basis in claims 2-4 and 6-10.

Claims 2, 3, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Mosesson et al (WO 98/12318) or Hubbell et al (US 2003/0064410).

Claim 2 is drawn to an isolated peptide comprising the motif of Formula I, wherein Y further comprises a peptido, glyco or lipo conjugate. Claim 11 is drawn in part to the isolated epitope of claim 2 further comprising a lipid, carbohydrate, peptide, glycolipid, glycoprotein, lipoprotein and/or LPS molecule. Claim 12 embodies an isolated epitope of claim 2 wherein said epitope is synthetic.

Mossesson et al disclose

(i) a peptide comprising the sequence HPAETEYESLYP (Registry No. 204975-91-7) wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-A-X, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, thus anticipating claim 2, wherein (Y)r has r=0 and wherein W=His, P(first)=Pro-

Ala, P(second)=Glu-Thr-Glu, (Y)t=sulfo-Tyr, P(third)=Glu-Ser-Leu, (Y)t=sulfo-Tyro and P(fourth)=Pro;

(ii) a peptide comprising the sequence HPAETEYESLYPEDD (Registry No. 204975-94-0), wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-X-A, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2; and also anticipating claim 5, wherein (Y)r has r=0 and wherein W=His, P(first)=Pro-Ala, P(second)=Glu-Thr-Glu, (Y)t=sulfo-Tyr, P(third)=Glu-Ser-Leu, (Y)t=sulfo-Tyro and P(fourth)=Pro-Glu-Asp-Asp, wherein m or n =2 for the final (A) group;

(iii) a peptide comprising the sequence AETEFESLYPEDD (Registry No. 204975-95-1), wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-X-A, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2;

(iv) a peptide comprising the sequence HPAEVEYEALYPEDD (Registry No. 204975-97-3), wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-X-A, sulfo-Tyr, X-A-A, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2; and also anticipating claim 5, wherein (Y)r has r=0 and wherein W=His, P(first)=Pro-Ala, P(second)=Glu-Thr-Glu, (Y)t=sulfo-Tyr, P(third)=Glu-Ala-Leu, (Y)t=sulfo-Tyro and P(fourth)=Pro-Glu-Asp-Asp, wherein m or n =2 for the final (A) group;

(v) a peptide comprising the sequence AETEYESLYPEDD (Registry No. 204975-96-2) wherein the sequence comprises the instant W=Ala, A-X-A, sulfo-Tyr, A-X-A, sulfo-Tyr, X-A-A, as evidenced by the attached Registry No. sequence, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2;

(vi) a peptide comprising the sequence AEVEYEALYPEDD (Registry No. 204976-00-1 and Registry No. 204976-03-4) wherein the sequence comprises the instant W=Ala, P(first)=Glu, P(second)=Val-Glu, sulfo-Tyr, P(third)=Glu-Ala-Leu, sulfo-Tyr, P(fourth)=Pro-Glu-Asp-Asp, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2;

(vii) a peptide comprising the sequence EALYPEDD (Registry No. 204976-02-3), wherein the sequence comprises W=0 by virtue of z=0, P=A-X-A, sulfo-Tyr, X-A-A, wherein the content of both "P" and "A" is chosen independently, and wherein the last occurring A=D and m or n for said A equals 2, thus fulfilling the specific embodiments of claim 2.

Mosesson et al disclose genetically engineered molecules combining two or more amino acid segments that are not naturally connected (page 4, lines 26-28, page 7, lines 1-35, page 8 lines 4-7 and 28-36), thereby fulfilling the specific embodiments of claim 2 regarding peptido conjugates and claim 11 further requiring a peptide. The disclosed peptides fulfill the specific embodiments of claim 2 with regard to being capable of binding to a human antibody or an antigen-binding fragment thereof, because the ability of binding to any given antibody is a function of the structure of the peptide. Mosesson et al disclose synthetic peptides (page 9, lines 23-24) which fulfill the specific embodiment of claim 12. Mosesson et al anticipate claim 3 because claim 3 allows Z=0, and therefore the requirement for W=glycine is moot.

Hubbell et al disclose

(a) the peptide comprising the sequence VFVSSVVSS (Registry No. 491841-54-4), wherein W=Val, P=(A)n(A)m(X)u, wherein m=0 and n and u=1, wherein (A)n=Phe and (X)u=Val, wherein t=2 and (Y)2=sulfo-Ser-Sulfo-Ser, wherein u and m=2, and n=0, wherein P=(X)u(A)m(A)n is Val-Val-Ser-Ser. The sulfo-Ser-sulfo-Ser fulfills the specific embodiment of claim 2 drawn to a peptido conjugate because the sulfo-Ser moiety is a peptido conjugate.; and

(b) the peptide comprising the sequence GGYDYG (Registry No. 491841-60-2), wherein W=Gly, P=(A)n(A)m(X)u, wherein m and u=0 and (A)n=G, sulfo-Tyr, P=(A)n(A)m(X)u, wherein m and u=0 and (A)n=Asp.

Hubbell et al disclose that the peptides may be associated covalently with a larger structure useful for delivering the peptides or modifying the uses of said peptides. Hubbell et al disclose examples of larger structures as any biocompatible structure, such as a synthetic polymer, protein, glycosaminoglycan, proteoglycan, liposomes (page 3, paragraph 0033), which fulfills the specific limitation of claim 2 with regard to a peptido or glyco or lipo conjugate and the limitations of claim 11 specifying a lipid, carbohydrate, peptide and lipoprotein. Hubbell et al disclose synthetic peptides (page 4, paragraphs 0037 and 0039) which fulfills the specific

limitation of claim 12. Mosesson et al anticipate claim 3 because claim 3 allows Z=0, and therefore the requirement for W=glycine is moot.

Claims 2 and 11-13 under 35 U.S.C. 102(b) as being anticipated by Leppanen et al (Journal of Biological Chemistry, 1999, Vol. 274, pp. 24838-24848) is maintained for reasons of record.

Claim 13 embodies the isolated epitope of claim 2 wherein said epitope comprises at least one post-translational modification in addition to sulfation.

Leppanen et al disclose the glycosulfopeptide-6 (GSP-6, page 24840, Figure 2) having the sequence GQATE-sulfo-Tyr-E-sulfo-Tyr-LD-sulfo-Tyr-DFLPETEPPEML having a sialyl Lewis carbohydrate motif on the Threonine of residue 57, thus fulfilling the specific embodiment of claim 13 specifying an additional post-translational modification, and the specific embodiments of claims 2 and 11 with regard to a glyco conjugate and an additional post-translational modification.. The disclosed peptide sequence fulfills the specific embodiments of claim 2 having W=Ala, X-A=Thr-Glu, sulfo-Tyr, A=Glu, sulfo-Tyr, AA=Leu-Asp-sulfo-Tyr, AAX=Asp-Phe-Leu to anticipate or W=Leu, A=Asp-sulfo-Tyr, A=Asp to anticipate claim 2. The disclosed peptide fulfills the specific embodiment of claim 12 requiring a synthetic epitope (figure 2).

Claims 2-4, 6-9, 10, 11,153, 154, 156 and 164 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al (Biochemistry, 1996, Vol. 35, pp. 4929-4938)

Ward et al disclose an isolated epitope comprising amino acid sequence Tyr276 to Glu282 of GPIb alpha (lines 14-16 of abstract) wherein at least one tyrosine residue is sulfated, this peptide also metes the specific embodiment of claim 156 which specifies the sequence YDYYPEE; an isolated epitope comprising amino acid sequence Tyr276 to Glu282 and further comprising residues 283-285 (page 4935, first column, lines 15-21) because Ward et al disclose the peptide consisting of residues 1-282 of GPIb alpha (page 4934, first column, line 12). It would be inherent in the peptide of residues 1-282 of GPIb alpha that at least one of amino acids 276, 278 and 279 is sulfated because the peptide comprises the sequence YDYYPEE which was disclosed by Ward et al to be 90% sulfated on Tyr 278 and 279 and 50% sulfated on Tyr 282.

Ward et al disclose the peptide of DEGDTDLYDYYPEEDTEGD (page 4930, first column, line 44) which fulfills the specific embodiments of claim 6 with (Y)r=0, because z=1, (W)z=Gly, P(first)=Asp-Thr-Asp as (A)n(X)u(A), P(second)=Leu as (A)n, wherein m and u=0, sulfo-Try, P(third) as (A)n=Asp, wherein m and u=0, t=2 and (Y)t=sulfo-Try-sulfo-Tyr, P(forth)=Pro-Glu-Glu-Asp as (X)u(A)n(A)m, wherein u and m=1 and n=2 and (X)u=Pro, (A)n=Glu and (A)m is Asp and also the embodiments of claims 7 because at least one A is Aspartate or Glutamate. Said epitope also fulfills the specific embodiment of claims 2 and 3 wherein z=0, P(first)=(A)n(X)u(A)m, wherein, n=u=m=1 and wherein (A)n=Asp, (X)u=Thr and (A)m=Asp; t=1 and (Y)t=sulfo-Try; and wherein P(second)=(A)m(A)n(X)u, wherein n and u are 0 and wherein (A)m is Asp. Ward et al disclose a peptido-conjugate comprising the sulfated peptide within the GP Ib-IX complex (page 4930, first column, lines 12-15) which fulfills the specific embodiments of claims 2, 3 and 6 and 8 requiring a peptido conjugate because the linkage of the peptide via the sulfonated tyrosines to the trimeric complex of GP Ib-IX is a peptido conjugate.

Applicant argues that the references do not disclose that said epitopes is capable of being bound by a human antibody, wherein said human antibody comprises a first hypervariable region comprising SEQ ID NO:8. This has been considered but not found persuasive. The peptides have the specific structural requirements of the claimed epitopes and therefore all would be "capable" of binding to an antibody comprising the hypervariable region of SEQ ID NO:8.

All other rejections and objections as set forth in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, PH.D.
5/29/2006

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PRIMARY EXAMINER